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EXAMINER

JOHANNSEN, DIANA B

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/936,523 | COLE ET AL. |
| | Examiner | Art Unit |
| | Diana B. Johannsen | 1634 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 January 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10,34-40 and 42-58 is/are pending in the application.
- 4a) Of the above claim(s) 3-10,34-37,39 and 42-58 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,38 and 40 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 14 September 2001 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 0202.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: Notice to Comply; sequence alignments.

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, and of the molecules of "Group E," in the Response of February 19, 2003 is acknowledged. It is further noted that Applicant clarified in the Remarks of January 30, 2004 that the elected molecules include RD9 and four molecules contained therein, *cobL*, Rv2073c, Rv2074, and Rv2075c, and that the claims readable on the elected invention are claims 1, 2, 38 and 40.

It is again noted that Applicant filed 3 replies in response to the Restriction Requirement of December 18, 2002. In the reply of February 19, 2003, Applicant traversed the rejection on the grounds that unity of invention was not lacking because the Brosch reference is not prior art to the instant application. However, in the reply of March 24, 2003, Applicant acknowledged (while not admitting that Brosch discloses the invention) that the Brosch reference in fact qualifies as prior art under 35 USC 102(b). In the reply of June 4, 2003, Applicant amended the claims, and traversed the restriction on the grounds that the Brosch reference does not disclose the invention of the claims as amended, as "Brosch et al. does not disclose a nucleotide or polynucleotide sequence deleted from the genome of *M. microti* OV254." The response argues that as the Brosch reference does not disclose the invention of Group I, unity of invention is not lacking. This argument has been thoroughly considered but is not found persuasive because the Brosch reference does in fact anticipate the invention as claimed (see

rejection under 35 USC 102(b) set forth below). Accordingly, unity of invention is lacking, for the reasons of record.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 3-10, 34-37, 39, and 42-58, as well as claims 1-2 and 40 to the extent that they are drawn to molecules other than those of RD9, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the replies of February 19, 2003 and June 4, 2003.

Specification

3. The disclosure is objected to because of the following informalities. On page 22, at line 20, the specification recites (immediately after the description of Figure 3) “FIGURE 4b.” No reference is made to Figure 4A. It is noted that the text below “FIGURE 4b” appears to describe both Figure 4A and Figure 4B; thus, the recitation of “FIGURE 4b” appears to be a typographical error. This objection could be overcome by replacing the recitation “FIGURE 4b” with “FIGURE 4.”

Appropriate correction is required.

4. The use of the trademarks HYBOND, PRIME-IT, and GENEAMP has been noted in this application. The trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Drawings

5. The drawings are objected to because the drawing that appears to correspond to the description of Figure 3 is not labeled as "Figure 3" (the drawing is not identified by a Figure number). It is noted that 37 CFR 1.84 (u)(1) requires Figures to be identified by number. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Compliance with Sequence Rules

6. The specification contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a) and (a)(2). However, the specification fails to comply with one or more of the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures, and further because the specification recites sequences that lack description by the appropriate sequence identifier set forth in the "Sequence Listing" as required by 37 CFR 1.821(d). See, for example, pages 49-50, and Figures 2A-2F. Appropriate corrections for compliance are required. Specifically, with regard to Figures 2A-2F, Applicant must provide a Sequence Listing that includes the sequences shown in the Figures. Further, Applicant must either file substitute Figures that recite the appropriate sequence identifiers, or amend the brief description of the figures so as to set forth said sequence identifiers. See MPEP 2422.02.

Regarding pages 49-50, the specification should be amended so as to recite the sequence identifier corresponding to each sequence.

Applicant is requested to return a copy of the attached Notice to Comply with the response to this Office action.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1, 2, 38, and 40 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1, 2, 38 and 40, as written, do not sufficiently distinguish over nucleic acids as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. For example, the claims as written appear to encompass a nucleic acid molecule as it exists within the genome of *M. tuberculosis*. In the absence of the hand of man, naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor. See MPEP 2105.

Claim Rejections - 35 USC § 112, second paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 2, 38, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 38, and 40 are indefinite over the recitation of the language “nucleotide or polynucleotide sequence” because it is not clear whether the claims are directed to a product (e.g., a nucleic acid molecule), or to information (i.e., a sequence, as opposed to a molecule/polynucleotide). Clarification is required.

Claims 1, 2, 38, and 40 are indefinite over the recitation of the limitation “deleted from the genomes of *M. bovis* BCG, *M. bovis*, and *M. microti* OV254” in claim 1. It is not clear whether the claims are limited to sequences that are naturally absent from the genomes of the three recited species/strains, or whether the claims in fact encompass any sequences that may be “deleted” from their genomes. The term “deleted” suggests, e.g., the performance by a practitioner of a deletion of particular nucleotides or polynucleotides from a molecule or genome; as any subsequence may be deleted from a polynucleotide or genome, it thus appears that the claims may encompass virtually any polynucleotide. Clarification is required.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1, 2, 38 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Brosch et al (Infection and Immunity 66(5):2221-2229 [5/1998]).

It is noted that the claims as written are sufficiently broad so as to encompass any “nucleotide or polynucleotide sequence” of any length. Thus, for example, claims 1-2 and 38 encompass any sequence of any length present in RD9, and claim 40 encompasses any sequence of any length present in any of the 4 recited regions of RD9. Further, the claims as written do not require that the sequences of the claims be, e.g., isolated or separated from the *M. tuberculosis* genome, but rather encompass the sequences irrespective of their location. Accordingly, simply by teaching *M. tuberculosis* H37Rv DNA (see, e.g., page 2222), Brosch et al anticipate the claimed invention, as the DNA taught by Brosch et al inherently include sequences meeting the requirements of the instant claims.

13. Claims 1, 2, 38, and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Fleischmann et al (U.S. Patent No. 6,294,328 B1 [9/2001; filed 6/1998]).

Fleischmann et al disclose the complete genomic sequences of *M. tuberculosis* H37Rv (Fleischmann et al's SEQ ID NO: 1) and CDC 1551 (Fleischmann et al's SEQ ID NO: 2). It is noted that the instant specification discloses that the strain of *M. tuberculosis* employed by Applicant was H37Rv, and further that an alignment of the

RD9-specific primers employed by Applicant (SEQ ID NOS 11 and 12; see specification page 11) share 100% identity with both SEQ ID Nos 1 and 2 of Fleischmann et al (see sequence alignments). Accordingly, Fleischmann et al teach polynucleotide sequences encompassed by the instant claims, and therefore anticipate the claimed invention.

14. Claims 1, 2, 38, and 40 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Gordon et al (Molecular Microbiology 32(3):643-655 [5/1999]). It is noted that the inventive entity of the instant invention is distinct from the authorship of the Gordon et al reference, and that this rejection may be overcome by the filing of a Katz-type declaration or by establishing priority of the invention to 3/16/1999 by filing a certified translation of French priority application 9903250.

Gordon et al disclose the RD9 region and the molecules contained therein that are encompassed by the instant claims (see entire reference, particularly Figure 2, Tables 1-3 and pages 649, right column-650, left column). Accordingly, Gordon et al clearly anticipate the claimed invention.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Diana B. Johannsen
Patent Examiner
April 28, 2004